



Advising the Congress on Medicare issues

Medicare coverage policy and use of low-value care

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Outline

- Low-value care
- 3 case studies of potentially low-value services
- Policy tools to address low-value care

Low-value care

- Definition
 - Services with little or no clinical benefit
 - When risk of harm from a service outweighs its potential benefit
- Potential to harm patients
 - Direct: Risks from low-value service itself
 - Indirect: Service may lead to cascade of additional tests and procedures that contain risks but provide little or no benefit
- Increases health care spending

Review of literature on low-value care

- Substantial use of low-value services in Medicare (Schwartz et al. 2014)
- Across all payers, 20% of patients in Virginia received a low-value service in 2014 (Mafi 2017)
- 15% of Medicaid patients and 11% of commercially insured patients in Oregon received a low-value service in 2013 (Charlesworth 2016)
- Amount of low-value care is more likely related to local practice patterns than payer type

Two analyses of low-value care in Medicare

- Examined selected low-value services in FFS based on 31 claims-based measures developed by Schwartz and colleagues
 - Examples: imaging for nonspecific low-back pain, stress testing for stable coronary disease, spinal injection for low-back pain
 - Same analysis presented in April 2017
- Analyzed 1 HEDIS® measure (PSA testing rates) in Medicare Advantage and FFS Medicare

Aggregate results from analysis of 31 low-value care measures in FFS Medicare, 2014

- 23%-37% of beneficiaries received at least one low-value service
- 34-72 low-value services per 100 beneficiaries
- Medicare spending on low-value care: \$2.4 billion-\$6.5 billion
- Results probably understate volume and spending on low-value care because measures are based on claims
- Spending estimates do not include downstream services that result from the initial service
- Substantial geographic variation
 - 5 of the 6 areas with highest adjusted number of low-value services are in Florida

Non-recommended PSA testing rates in Medicare Advantage and FFS Medicare

- MA plans report rates of non-recommended PSA testing for men age 70 or older
- Because the measure uses administrative data and applies to large segments of the population, MA results can be compared to FFS results by market area and within markets
- Compared results for 113 metro areas with large MA HMO enrollment
- Variation in both MA and FFS by area

Selected metropolitan areas with high and low rates of non-recommended PSA testing

Metropolitan area	MA percentile rank	FFS percentile rank
High relative MA rate		
Miami-Miami Beach, FL	1.00	1.00
Fort Lauderdale-Pompano Beach, FL	0.95	0.93
West Palm Beach-Boca Raton, FL	0.92	0.99
Low relative MA rate		
Sacramento-Roseville, CA	0.02	0.27
Minneapolis-St. Paul, MN-WI	0.08	0.03
Albuquerque, NM	0.09	0.14

Note: PSA (prostate-specific antigen), MA (Medicare Advantage), FFS (fee-for-service Medicare)
 Source: MedPAC analysis of 2017 HEDIS data and 2015 FFS claims data.

Case studies of potentially low-value services

- Early initiation of dialysis
- Proton beam radiation therapy
- H.P. Acthar Gel (drug covered by Part D)

Case study 1: Early initiation of dialysis

- “Early starts” for dialysis increased from 13 percent in 1996 to 44 percent in 2010
 - Started to decrease in 2011, but not to earlier levels
- The increase is linked to multiple factors, including early observational research and clinical guidelines
- Recent studies (including a randomized controlled trial) indicate that outcomes do not improve with earlier initiation
- In 2016, Medicare spending for dialysis treatments due to “early starts” estimated to range from \$500 million to \$1.4 billion

Note: An “early start” is typically measured as having an estimated glomerular filtration rate (one measure of kidney function) of ≥ 10.0 mL/min/1.73m² at dialysis initiation. Results preliminary and subject to change.

Case study 2: Proton beam therapy

- Initially used for rare adult and pediatric cancers, but now also used for more common cancers
- Lack of evidence that it offers a clinical advantage over alternative treatments for common cancers
- Rapid growth in number of proton beam centers
- Medicare payment rates for proton beam much higher than other types of radiation therapy
- Medicare has few coverage restrictions
- Medicare volume and spending more than doubled from 2010-2016
 - Spending increased from \$47 million to \$115 million

Case study 3: H.P. Acthar Gel

- Injectable biologic approved by FDA in 1952
- Indicated for treatment of infantile spasms and 8 other conditions (e.g., exacerbations of multiple sclerosis)
- Lack of strong evidence that it is effective for adult conditions
- Availability of cheaper, effective alternatives
- After acquisition by Questcor, average price per vial grew from \$748 in 2001 to \$34,000 in 2014
- After acquisition by Mallinckrodt, price per vial increased to \$38,000 in 2017

Case study 3: H.P. Acthar Gel (cont.)

- Most Part D plans did not cover Acthar Gel in 2017
- Part D spending for Acthar Gel rose from \$49 million in 2011 to \$504 million in 2015
- 1,743 clinicians prescribed Acthar Gel to 3,104 beneficiaries (2015)
- Spending per beneficiary = \$162,000
- Most prescribers (71%) have financial relationship with manufacturer, based on Open Payments data

Policy tools to address low-value care

- Prior authorization for certain types of services
- Clinician decision support and provider education
- Altering beneficiary cost sharing
- Delivery system reform/new payment models
- Linking evidence of comparative clinical effectiveness and cost effectiveness to coverage and payment

Prior authorization for certain types of services

- Three CMS prior authorization demonstrations produced savings
 - Power mobility devices (Sept. 2012-present)
 - Repetitive scheduled non-emergent ambulance transports (Dec. 2014-present)
 - Non-emergent hyperbaric oxygen therapy (March 2015-March 2018)
- National prior authorization process for durable medical equipment (currently applies to 2 power wheelchair products)
- Commission recommended prior authorization for clinicians who use substantially more advanced imaging services than their peers (June 2011)

Clinician decision support and provider education

- Evidence that clinician decision support and provider education/feedback reduces inappropriate use of antibiotics
- CMS developing program to require clinicians who order advanced imaging to use decision support software and obtain feedback on whether imaging is appropriate
- Issue: Clinical guidelines are sometimes in conflict with each other

Altering beneficiary cost sharing

- Reducing cost sharing should encourage use of high-value services; increasing cost sharing should discourage use of low-value services
- Commission recommendation to give Secretary authority to alter cost sharing based on evidence of value of services (2012)
- CMS does not currently increase cost sharing for low-value services
- Study of public employer in Oregon: Increased cost sharing for low-value services reduced use (Gruber et al. 2016)

Delivery system reform/new payment models (e.g., ACOs)

- ACOs take responsibility for cost and quality of care
- Limited evidence that 2-sided risk ACO models decrease low-value services while other ACOs do not
 - Pioneer ACOs (2-sided risk) had greater reduction in volume and spending for low-value care than a control group of other beneficiaries (Schwartz et al. 2015)
 - Medicare Shared Savings Program ACOs (1-sided risk) did not affect use of low-value care during first year (McWilliams et al. 2016)

Linking evidence of comparative clinical effectiveness and cost effectiveness to coverage and payment

- Medicare's coverage process
 - Considers, but does not require, comparative clinical effectiveness evidence
 - Generally does not consider cost-effectiveness evidence
- Medicare's payment systems generally do not consider whether a new service results in better outcomes than alternatives
- Prior to 2010, Medicare set the payment rate for groups of drugs that treat the same condition and produce the same outcome based on the least costly drug

Example of linking comparative clinical effectiveness evidence to payment

Clinical evidence	Proposed payment rate
Evidence of improved outcomes compared with alternative	Set according to usual statutory formulas
Evidence of similar outcomes compared with alternative	Equal to alternative treatment
Insufficient evidence to assess comparative effectiveness	Set according to usual statutory formulas for 3 years; at end of period, reevaluate evidence and adjust payment accordingly

Source: Pearson and Bach 2010.

Summary

- June 2018 report chapter issues
 - FFS Medicare's coverage process
 - Use of low-value care and potentially low-value care in Medicare
 - Policy tools to address low-value care
- Clarifications about material

Some categories of low-value care account for most of volume, spending

	Broader version of measures	Narrower version of measures
Categories that account for most volume	<ul style="list-style-type: none"> • Imaging • Cancer screening 	<ul style="list-style-type: none"> • Imaging • Diagnostic and preventive testing
Categories that account for most spending	<ul style="list-style-type: none"> • Cardiovascular tests/procedures • Other surgical procedures 	<ul style="list-style-type: none"> • Other surgical procedures • Imaging